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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,192	03/01/2002	David W. Morris	529452000122	7201

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,192	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11 and 20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11 and 20-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/28/03; 12/29/03; 09/20/04; 12/15/04.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V (claims 10, 11 and 20-38) in the reply filed on May 9, 2007 is acknowledged. The traversal is on the ground(s) that "...examining more than one invention would not constitute a serious burden". This is not found persuasive because as indicated in the Requirement mailed March 21, 2007 each individual Group reflects patently distinct products and methods, see page 5 of Requirement mailed March 21, 2007. Furthermore, Applicants have cancelled the remainder of claims that read on other distinct and separate groups.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 10, 11 and 20-38 are pending.

Claims 1-9 and 12-19 are cancelled.

Claims 10 and 11 have been amended.

Claims 20-38 have been added.

Claims 10, 11 and 20-38 are examined on the merits.

Priority

3. Claims are granted one priority date based upon when all the limitations of the claims were of record. The Examiner has reviewed the continuation in part applications (CIP), U.S. Application 09/747,377 (filed December 22, 2000) and 09/798,586 (filed March 2, 2001). The claims read on methods encompassing sialophorin and SEQ ID

NO: 1175. These limitations have not been found in the applications in which Applicants claim priority. The Examiner is not clear if Table 1 of the instant application is the same as Table 1 presented in applications '377 and '586. All of the limitations of the claims were not disclosed until the filing of the instant application. Accordingly, claims 10, 11 and 20-38 are granted the priority date of the instant filing date of March 1, 2002.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed October 31, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Only one of the fourteen references listed has been considered. The remainder of the references is noted in the application file, but the information referred to therein has not been considered. Applicants should also provide dates of the references listed therein.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 10, 11 and 20-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing bladder

carcinoma, colon cancer, breast cancer or prostate cancer comprising detecting evidence of differential expression of sialophorin gene (SEQ ID NO: 1175) in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of sialophorin and wherein the expression product is a mRNA having a sequence of SEQ ID NO: 1175, does not reasonably provide enablement for the said method measuring a full complement of the mRNA sequence of SEQ ID NO: 1175 (sialophorin). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In essence, mRNA is art known as a single-stranded RNA molecule that is synthesized during transcription and is complementary to one of the strands of double-stranded DNA. A protein encoded from the mRNA, based on translation of the complementary sequence from 5' to 3', would not bear any resemblance to the protein encoded from SEQ ID NO: 1320 and hence would not be applicable to the claimed method.

7. Claims 11, 23 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claim method for diagnosing cancer comprising detecting SEQ ID

NO: 1175 in a patient sample and diagnosing cancer comprising determining the level of expression product having at least 98% sequence identity to a sequence of SEQ ID NO: 1175, or a full complement thereof. The written description is not commensurate in scope with these method claims drawn to a method of detection of mRNA sequences 98% sequence identical to SEQ ID NO: 1175 or full complements thereof, which have not been adequately described nor evidenced to be in the possession of Applicants. Applicants seem to only be in possession of SEQ ID NO: 1175. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identify characteristics sufficient to show that the applicant was in possession of the claimed invention", see Official Gazette, 1242 OG 172, January 30, 2001.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of nucleotide sequences

having 98% or less identical to SEQ ID NO: 1175, as well as full complements thereof, and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not described nucleotide sequences at least 98% identical to SEQ ID NO: 1320, as well as complements thereof with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 10, 11, 20, 21 and 23-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 10, 11, 22 and 34 recite methods of evaluating the effectiveness of a candidate carcinoma drug comprising contacting said drug with a cell that expresses sialophorin and determining alterations in the expression or activation of sialophorin gene and diagnosing carcinoma, as well as measuring the level of sialophorin gene expression. However, the claims do not contain steps describing the how alterations are assessed. And while all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced. The method steps should at least include reagents necessary for the assay, a detection step in which the reaction products are quantitated or visualized and a correlation step describing how the results of the assay allows the determination of for example, the analysis of activation or lack of the sialophorin gene.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 10, 11 and 20-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001). The application publication discloses genes, such as sialophorin also art known as leukosialin change in various stages or grades of bladder cancer and can be used as markers for drug screening, see page 5, section 0063; page 88, gene name J04168; page 129, gene name M61827; and page 203, gene name X52075. The application asserts by treating bladder cancer cells with the test compounds and monitoring the expression of said genes identified as changing in the progression of bladder cancers, one can identify compounds, which change expression of genes and thereby determining whether or not the test compound is an effective carcinoma drug, see page 2, section 0025.

Applicants have identified SEQ ID NO: 1175 as human sialophorin, see Remarks submitted May 9, 2007, page 5, 2nd paragraph. Consequently, the disclosed sialophorin of the patent application publication is the same as Applicants' SEQ ID NO: 1175. The publication discloses evaluating assays, which may be used to assess gene expression patterns wherein patient samples are assayed, see page 1, sections 0017 and 0018; and page 4, sections 0056-0058. Given the sialophorin is the same as that claimed, as well as the active method steps are the same, the prior art reads on detection of colon, breast and prostate cancer.

12. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2007/0037165 A1 (effective filing date September 8, 2000). The patent discloses sequence 2380 that is the same as Applicants' SEQ ID NO: 1175 (sialophorin), see attached database sheet. The publication also discloses methods of treatment with candidate compounds, drugs or modulators, wherein the said molecules are identified as stimulators or inhibitors of the sialophorin expression, see pages 16 and 17, sections 0170 and 0171, respectively. These disclosures read on the identification of an effective carcinoma drug.

13. Claims 10, 11 and 20-38 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2006/0194265 A1 (effective filing date February 27, 2002). The publication discloses sequence 646, which shares 100% sequence homology with Applicants' SEQ ID NO: 1175 (sialophorin), see attached database sheets. The publication discloses methods of screening for anticancer activity comprising: (a) providing a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid sequence selected from the group consisting of the CA sequences shown in Tables 1-124 (i.e. sequence 646), or fragment thereof; (b) contacting a tissue sample derived from a cancer cell with an anticancer drug candidate; (c) monitoring an effect of the anticancer drug candidate on an expression of the CA polynucleotide in the tissue sample, and optionally (d) comparing the level of expression in the absence of said drug candidate to the level of expression in the presence of the drug candidate.", see page 2, section 0017; page 4, section 0022; and page 5, section 0027.

The publication also discloses diagnosing carcinomas, colon, breast and prostate cancers by comparing the level of expression of the polypeptide in the test sample with a level of expression and activity of a polypeptide in a normal cell sample, wherein an altered level of expression and activity of the polypeptide in the test cell sample relative to the level of polypeptide expression and activity in the normal cell sample is indicative of the presence of cancer in the test cell sample, see pages 5-7, sections 0028, 0029 and 0032, respectively; page 8, section 0044; page 9, section 0045. The "CA sequences are those that are up-regulated in cancers; that is, the expression of these genes is higher in cancer tissue as compared to normal tissue of the same differentiation stage. "Up-regulation" as used herein means increased expression by about 50%, preferably about 100%, more preferably about 150% to about 200%, with up-regulation from 300% to 1000% being preferred.", see page 12, section 0065.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
23 July 2007